Exhibit B

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Original Contribution

Prolonged TASER use on exhausted humans does not worsen markers of acidosis☆,☆☆

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Abstract

Objective: There are safety concerns about TASER conducted electrical weapon (CEW) use on humans, and there have been media reports of adverse human outcomes after CEW exposure. Conducted electrical weapons are often used on physically exhausted subjects. A single CEW application of a CEW is generally accepted to be 5 seconds of exposure. Some exposures in reality involve more than 5 seconds. We sought to determine if a prolonged (15 seconds) CEW exposure on exhausted humans caused acidosis, hyperkalemia, serum lactate change, or troponin change.

Methods: This was a prospective study of generally healthy human volunteers. Medical histories and baseline serum values were obtained, and several of the volunteers did have acute or chronic medical problems. Subjects underwent an exercise protocol until subjective exhaustion. Exhaustion was defined by the volunteer no longer being able to perform the exercise at a given pace. Blood was drawn immediately (defined as within 20 seconds) after exercise and was immediately followed by a 15-second CEW exposure. Blood was drawn immediately after exposure and again at 16 to 24 hours after exposure. Blood was analyzed for pH, pCO_2, potassium, lactate, and troponin. Data were compared using Wilcoxon signed rank tests.

Results: There were 38 subjects enrolled with an average age of 39 years. The following health conditions were reported among the volunteers: hypertension (2), gastritis/reflux (2), active respiratory tract infections (3), asthma (2), chronic muscular pain conditions (4), pituitary adenoma (1) and glaucoma (1). Sixteen volunteers reported use of prescription medication at the time of their participation. The median initial pH of 7.38 (interquartile range [IQR], 7.35-7.40) decreased to 7.23 (IQR, 7.19-7.31) immediately after exercise. Immediately after exposure, median pH was 7.22 (IQR, 7.18-7.25). It was 7.39 (IQR, 7.37-7.43) at 24 hours. The pCO_2 increased from 46.3 (IQR, 43.0-54.5) to 57.4 (IQR, 49.9-67.7) immediately after exercise, decreased to 51.3 (IQR, 44.4-65.0) immediately after exposure, and was

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46.3 (IQR, 42.7-51.7) at 24 hours. Lactate increased from a median of 1.65 (IQR, 1.14-2.55) to 8.39 (IQR, 6.98-11.66) immediately after exercise, increased to 9.85 (IQR, 7.70-12.87) immediately after exposure, and was 1.02 (IQR, 0.91-1.57) at 24 hours. Serum potassium increased from 3.9 (IQR, 3.8-4.4) to 4.2 (IQR, 4.0-4.9) immediately after exercise, decreased to 3.8 (IQR, 3.7-4.4) immediately after exposure, and was 4.1 (IQR, 3.9-4.6) at 24 hours. No troponin elevations were detected.

Conclusion: Prolonged CEW application on exhausted humans was not associated with worsening change in pH or troponin. Decreases in pco_2 and potassium and a small increase in lactate were found. Worsening acidosis theories due to CEW use in this population are not supported by these data.

1. Introduction

The conducted electrical weapon (CEW) is currently available for law enforcement and civilian use. It is designed to subdue or repel agitated or violent individuals. It has come under scrutiny by national and international media and human rights organizations because there have been unexpected deaths of persons in custody after its use [1,2]. Although most deaths in police custody occur when no CEW has been applied (70%) [3], a causal association has been suggested in the lay press [4-6].

Theories about this association have included production of immediate fatal arrhythmias or some type of delayed organ system damage that manifests itself as sudden death at a later period [7]. Previous work in this area has not demonstrated a dangerous effect on human volunteers [8,9]. However, this work was performed on volunteers in a rested state. In reality, CEW use is often applied to subjects in the field who have physically exhausted themselves just before the application and may continue to exert themselves throughout the arrest and control process. This exhaustion is usually due to profound agitation or fleeing from and resisting law enforcement. Intense struggling is an activity that has been associated with sudden custodial deaths [10]. There is rested animal data to suggest that CEW application under laboratory circumstances can lead to worsening acidosis [11]. It is not known what effect a CEW might have on a physically exhausted human subject. The objective of this study was to determine if CEW exposure caused worsening acidosis, hyperkalemia, increased serum lactate, or cardiac injury in subjects who had undergone an exercise protocol to induce physical exhaustion immediately before CEW exposure.

2. Methods

2.1. Study design

This was a prospective nonclinical study of adult volunteers recruited at a TASER International training course in May 2006. The institutional review board of Hennepin County Medical Center approved the study. All subjects provided informed consent before enrollment.

2.2. Study setting and population

This study was performed with volunteer human subjects attending a training course. As a voluntary part of their training course, they were to receive a CEW exposure from a TASER device. All adult subjects (age >18 years) who were going to receive this exposure were eligible for enrollment in the study. All volunteers were personnel involved in various aspects of medicine or law enforcement. They did not have to participate in the study as a requirement for successful course completion, but declining to participate in the study did not absolve them from receiving a CEW application as part of their training course. The exclusion criteria were known pregnancy and known mental illness diagnoses. The study site had standard resuscitation equipment available to the investigators in the event that an adverse event was to occur. Volunteers were given a TASER X26 CEW upon successful completion of the study protocol.

2.3. Study protocol

All volunteers completed a medical questionnaire for the purpose of gathering additional medical information for descriptive reporting. The descriptive data points gathered for all subjects included age, sex, body mass index (BMI) parameters, past medical history, and current medication use. After completion of the study questionnaire, all volunteers had blood drawn before the CEW application for baseline laboratory analysis of venous pH, pco_2, lactate, potassium, and troponin.

Upon completion of the baseline laboratory analysis, each volunteer performed a series of intense, rigorous physical activities designed to invoke anaerobic exhaustion. This activity began with a 30-second timed period of push-ups. The volunteer was instructed to perform as many push-ups as they were able to during this period. If they could not continuously perform push-ups for the 30-second duration, they were allowed to rest in the "up" position (arms at full extension, feet in contact with the floor) until they could continue. Immediately (defined as within 20 seconds) after this period of push-ups, the volunteer was placed on a treadmill that was moving at 8.0 mph at 8° of elevation. They were instructed to run until they could no longer keep up with the pace of the treadmill. At this point, they were

Fig. 1 TASER X26 CEW.

defined as being subjectively exhausted and immediately underwent venipuncture for repeat serum biomarker evaluation by an investigator who was at the subject's side throughout the protocol.

Volunteers then underwent the CEW application. This consisted of a 15-second application with applied electrodes powered by the TASER X26 model CEW (Fig. 1; TASER International, Scottsdale, AZ). The exposure consisted of manually applying electrodes to the volunteer while they were lying on a padded mat in a supine position. The electrodes were manually placed instead of fired from the CEW at the subject to assure exact placement from volunteer to volunteer. The electrodes were placed on the subject's trunk in positions to span a majority of the trunk while including transdiaphragmatic positioning. Common placement included ipsilateral and contralateral positioning at shoulder and hip, pectoral region and leg, and scapula and buttock. The electrodes were connected to a factory standard TASER X26 CEW. A programmable logic controller (PLC) was used to accurately control the duration of current delivered (Allen-Bradley MicroLogix 1500, Maple Systems, Inc, Everett, WA). The purpose of the PLC was to enable the CEW current application to be delivered in an objective, reproducible, and controlled fashion. With the exception of this PLC, the CEW was not altered from the factory standard. The PLC was programed to deliver the CEW discharge for a total of 15 continuous seconds. Immediately after the CEW application, all subjects underwent a third venipuncture by the investigators. Upon completion of the application protocol, the electrodes were removed, the attachment points were disinfected, and adhesive bandages were applied if needed.

All subjects had venipuncture performed a fourth time between 16 and 24 hours after the application. The variation of time between 16 and 24 hours was necessary to accommodate the data collection process because these activities were time consuming and occurred over an 8-hour period.

All collected blood samples were analyzed for venous pH, pCO_2, lactate, serum potassium, and troponin I. Venipuncture was performed by research physicians or certified

Table 1 Summary data

	Baseline	Time 2	Time 3	Time 4
pH				
Median	7.38	7.23	7.22	7.39
Range	7.229-7.448	6.999-7.356	7.084-7.457	7.329-7.444
IQR	7.35-7.40	7.19-7.31	7.18-7.25	7.37-7.43
Comparison to previous (Wilcoxon signed rank)		$P < .001$	$P = .71$	$P = .12$ (comparison to baseline)
pCO_2				
Median	46.3	57.4	51.3	46.3
Range	33.2-59.7	36.0-87.4	25.8-69.6	34.1-53.6
IQR	43.0-54.5	49.9-67.7	44.4-65.0	42.7-51.7
Comparison to previous (Wilcoxon signed rank)		$P < .001$	$P = .04$	$P = .88$ (comparison to baseline)
Lactate				
Median	1.65	8.39	9.85	1.02
Range	0.5-8.5	2.1-16.5	1.2-15.2	0.5-2.8
IQR	1.14-2.55	6.98-11.66	7.70-12.87	0.91-1.57
Comparison to previous (Wilcoxon signed rank)		$P < .001$	$P = .04$	$P < .001$ (comparison to baseline)
K				
Median	3.9	4.2	3.8	4.1
Range	3.5-5.3	3.3-5.3	3.3-4.7	3.6-4.6
IQR	3.8-4.4	4.0-4.9	3.7-4.4	3.9-4.6
Comparison to previous (Wilcoxon signed rank)		$P < .001$	$P < .001$	$P = .03$ (comparison to baseline)
Troponin				
Mean	0.0	0.0	0.0	0.0
Range	0-0.01	0-0.01	0-0.01	0-0.01

phlebotomists. After each venipuncture, the specimens were labeled and analyzed immediately on a portable i-STAT point of care analyzer (Abbott Diagnostics, Abbott Park, IL).

2.4. Data analysis

Data were entered in an Excel (Microsoft Excel 2003, Redmond, WA) spreadsheet for analysis. Data analysis was performed using STATA 10.0 (STATA Corp, College Station, TX). Descriptive statistics were used when appropriate. The median, interquartile range (IQR), and ranges of laboratory values for pH, pCO_2, lactate, and potassium are presented for comparison and were compared between time points using Wilcoxon signed rank tests. Power analysis of the Wilcoxon signed rank test revealed that to detect a 10% difference between baseline and subsequent laboratory values, with a significance of .05 and a power of 90%, 37 subjects were required.

3. Results

A total of 38 human volunteers were enrolled in the study. There were 36 men and 2 women enrolled. The average age was 38.9 years (range, 21-48). All postexercise and post-exposure blood draws were completed at the moment the exercise or exposure concluded. The mean time the 24-hour laboratory sample was obtained was 20.6 (±0.36; range, 16-24) hours after the exposure. All subjects completed the exhaustion protocol and the laboratory testing except for a single subject who did not have the fourth blood sample obtained. This subject left the instructional course early to return home and was unavailable for final venipuncture.

The mean volunteer BMI was 28.6 ± 4.2 (range, 17.4-37.2). Twenty-eight subjects did not note any significant past medical history, 2 reported hypertension, 2 reported chronic gastritis/reflux, 3 had active current upper respiratory tract infections, 2 had asthma, 4 with musculoskeletal pain chronically, 1 reported a pituitary adenoma, and 1 had a history of glaucoma. A total of 21 subjects reported they were not on any medications, 7 were on non-steriodal anti-inflammatory drugs (NSAIDS), 4 were on allergy medications, 2 were on steroid and albuterol inhalers for asthma, 1 was taking antibiotics, 1 was on an ace inhibitor, and 1 was taking an H2 blocker.

Data are summarized in Table 1. The median initial pH of 7.38 decreased to 7.23 after the exercise protocol ($P < .001$). After the exposure, the median remained 7.22 ($P = .71$). It returned to the baseline median of 7.39 at 24 hours ($P = .12$). The pCO_2 increased from 46.3 to 57.4 during the exercise protocol ($P < .001$), decreased to 51.3 after CEW exposure ($P = .04$), and was similar to baseline at 46.3 at 24 hours ($P = .88$). The lactate increased from a median of 1.65 to 8.39 during the exercise protocol ($P < .001$), increased to 9.85 after CEW exposure ($P = .04$), and was decreased from baseline to 1.02 at 24 hours ($P = .006$). The serum potassium increased from 3.9 to 4.2 during the exercise protocol ($P < .001$), decreased to 3.8 after CEW exposure ($P = .001$), and was increased to 4.1 from baseline after 24 hours ($P = .003$). No elevations in troponin were detected in any of the subjects at any time point.

4. Discussion

Conducted electrical weapons are becoming increasingly popular force options for use by some law enforcement agencies [12]. Conducted electrical weapons are categorized as nonlethal weapons by the United States Department of Defense and offer law enforcement personnel another option for control of agitated or potentially violent persons [13]. Agitated persons confronted by law enforcement have been demonstrated to often be in a state of severe exhaustion and metabolic acidosis [14]. It is not clear whether this state of exhaustion, coupled with the application of a CEW might lead to adverse acidosis parameters.

The term *TASER* is an acronym for Thomas A. Swift's Electric Rifle and is a name based on a fictional series of children's literature involving hi-tech solutions to problems and conflicts. Our work focused on the TASER X26 model of CEW. The rationale for this is that it is currently the most popular CEW in use by law enforcement officials and is the model most likely to be encountered in the field.

Previous human work in this area has demonstrated minimal effects with a 5-second application from a TASER X26 CEW on rested volunteers [9]. In this prior work by Ho et al [9], markers of cardiac and cellular damage were examined as were electrocardiograms of a subset of the volunteers over a 24-hour period after CEW exposure. There was no change in the electrocardiograms, and there were no statistically significant changes in the biomarkers for cardiac and cellular damage such as serum troponin and potassium. There was an elevation of serum creatine kinase, which was expected because CEW application induces vigorous skeletal muscle activation. The elevated creatine kinase levels seen were on the order of what would be expected in a human subject after engaging in a strenuous athletic event [15]. A single subject had a troponin elevation, which was dismissed after an extensive, independent cardiology evaluation. This is of interest because other authors have found troponin elevations after athletic activity in human subjects [16].

In this study, we elected to have our volunteers exert themselves to exhaustion. We initially entertained the idea of having the volunteers follow an established protocol for a cardiac exercise stress test but abandoned this after deciding that this protocol was more appropriate for subjects with suspected or known coronary artery disease. This parameter did not describe our volunteer population to our knowledge. In the end, we decided to allow subjective exhaustion to be

the guide, and our volunteers were instructed to perform the exercise event until exhaustion. Their level of exhaustion was objectively measured by their venous pH status immediately before and after the event. We believe that this allowed us to truly test for the effect that exhaustion has when coupled with CEW application.

Our volunteer population was made up of either law enforcement officers or physicians. This was because these 2 categories of professionals were available for recruitment. Because our study was performed during a law enforcement instructional class and physicians were present to collect the data, these 2 categories were the only ones available to us for testing. A concern might be that our volunteer population might be more physically fit than other populations that CEWs might be used upon in realistic situations. This is recognized and is addressed as a potential limitation of our study. However, it is important to note that the mean BMI (overweight) of our volunteer population does not suggest an above-average level of fitness.

We also elected to measure the serum potassium and troponin I levels in our volunteer population because they can be indicators of cellular and myocardial injury. Previous work has not shown either of these biomarkers to exhibit significant change with CEW application [9]. However, it has never been measured in an exhausted population after a prolonged exposure. In this study population, we were also not able to demonstrate a significant change.

In addition, we extended the CEW application time from 5 seconds in the previous Ho et al study to 15 continuous seconds. We believe that this prolonged time may more accurately reflect some field usage patterns because some agitated subjects require more than a single CEW application. A single CEW application is considered to be a single depression of the trigger, which would result in a 5-second discharge from the CEW. Alternatively, the CEW trigger could be depressed continuously resulting in a CEW discharge for as long as the trigger is depressed. Current information from the manufacturer suggests that most CEW exposures in the field are for 5 seconds or less (S. Tuttle, personal communication, April 17, 2007). Another reason that we studied prolonged application times was to increase the chance of uncovering an adverse effect if one were to be found.

There has been some controversy about a recent animal model study that demonstrates CEW induced acidosis in rested swine [11]. Conducted electrical weapon critics have pointed out that this study by Jauchem et al [11] is reasonable proof that a human being in an exhausted condition should exhibit significantly greater acidemia after CEW application [17]. We believe Jauchem's cautionary statements to be correct in that they warn readers to not draw full conclusions between his study and real law enforcement use on humans due to methodology limitations [18]. Our data would also support Jauchem's statements because our findings in humans did not mimic his in swine.

There was a significant increase in serum lactate that occurred after the exercise protocol. This level increased a small but statistically significant amount after the CEW exposure and returned to baseline at the 24-hour postapplication time. Lactate is a by-product of exercise and metabolism, and the elevation after the exercise event was expected. We believe that the small elevation after CEW exposure is most likely due to the continued elevated metabolic level from the exercise event because the CEW exposure and the subsequent venipuncture took place immediately after the subjects came off of the treadmill and it is unlikely that recovery from the exercise event occurred within such a short amount of time.

Additional work has been published that demonstrates human subjects tend to breathe above their baseline parameters during prolonged CEW application. This is an important conclusion relative to our findings because continued ventilation during CEW exposure of an acidotic subject should only serve to improve an altered acid-base state [19]. The demonstration by this study that CEW application to an exhausted cohort did not demonstrably worsen their acidotic condition has ramifications beyond simple acid-base physiology. This study suggests that the modern-day practice of using a CEW to subdue or repel an agitated, exhausted individual may not be life-threatening.

From a law enforcement perspective, the tools and tactics generally available to most law officers work from the perspective of inducing compliance through painful stimulus. This is the principle that pepper spray, impact weapons, and "empty hand" control techniques work from. Law enforcement officials often encounter subjects who are exhibiting conditions consistent with marked acidosis [14]. These conditions collectively are described by many experts to be a syndrome known as excited or agitated delirium [20]. Subjects in an excited or agitated delirium condition demonstrate a significant decrease in pain perception and can often continue to fight, flee, and resist even when these painful stimuli are applied repeatedly. The condition of excited delirium appears to occur simultaneously with significant metabolic acidosis, and death has occurred in association with this condition [14]. Modern-day CEWs demonstrate the ability to apply a painful stimulus but also cause physiologic muscle incapacitation that cannot be overcome by a delirious condition. Our study supports the idea that CEW use on agitated, dangerous, and exhausted individuals represents an acceptable method of control that does not appear to worsen an acidotic condition that is already present. This may represent a potentially life-saving control method when compared with other means of force such as impact weapons or firearms.

4.1. Limitations

One of the limits of this study is the relatively small number of subjects enrolled. However, in light of the small number of volunteers willing to endure a prolonged CEW exposure because of the discomfort involved, it would be difficult to conduct this same methodology with very large

numbers of volunteers. We believe that the number of volunteers that we have tested is adequate to detect evidence of physiologic impairment due to CEW exposure. We encourage future studies with similar methodology to validate our results.

Another limit of this study is that our study population did not exactly mimic the characteristics of human subjects that tend to have custodial death events. Literature indicates that in custodial death situations, the persons that die tend to have mental illness with psychotic features or illicit stimulant abuse histories [21]. These factors were presumably not present in our volunteer population. However, we do not believe that this limit equates to a "healthy population bias." The volunteers that we studied were not young and did not have exceptional levels of physical fitness. They had a wide age range, and some had medical problems that required controlling medication. In addition, their average BMI calculations place them in the "overweight" category by federal standards [22]. Although our study population most likely did not have a history of psychosis or chronic illicit stimulant abuse, which are common descriptors of persons who die suddenly in custody [23], they do appear to represent the average adult citizen of this country.

5. Conclusion

Prolonged CEW application on exhausted, acidotic volunteers was not associated with a further change in pH or an elevation in serum troponin. It was associated with a small decrease in pco_2, a small increase in lactate, and a small decrease in potassium. Prolonged CEW exposure in exhausted humans does not appear to result in worsening acidosis, hyperkalemia, or cardiac injury but was associated with a small increase in serum lactate.

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